K081800

SEP 2 4 2008

510(k): Device Summary

Submitter:

Laura Spiegelhoff, Manager of Quality Assurance / Regulatory Affairs
Mortara Instrument, Inc.
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Milwaukee, WI 53224
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Contact: Laura Spiegelhoff (see above)

Trade Name: T12S Telemetry Transmitter
Common Name: Telemetry Transmitter
Classification Name: The following Class II classifications appear to be applicable:

Device Name	Classification Name	CFR Section
T12S Telemetry Transmitter	Transmitters and Receivers, Physiological Signal, Radiofrequency	870.2910
	Oximeter	870.2700

Legally marketed devices to which S. E. is claimed

The T12S Telemetry Transmitter is an evolution of a legally marketed Mortara predicate device and is also substantially equivalent to other devices presently in distribution.

- Mortara Ambulatory X-12 Telemetry Module, (K974149)
- General Electric Apex Pro (K000779)
- Spacelabs Telemetry (K983996)
- Philips Intellivue (K993516)

Description:

The T12S and T12 Telemetry Transmitters are non-invasive prescription devices positioned for typical use within a clinical setting of ambulatory patients in a centralized monitoring system or other clinical settings where such telemetry is used. The Telemetry Transmitters are patient-worn diagnostic tools intended to acquire, and transmit real time ECG and SpO2 data of ambulatory patients that require ECG monitoring during cardiovascular problematic situations.

When used within a compatible multi-parameter Telemetry Central Station system, the Transmitters are designed to transmit ECG data only (T12 version) or ECG and SpO2 data (T12S). The mode will be selectable. The Transmitters will typically be used for centralized ECG monitoring in a telemetry system consisting of three main components: the ambulatory ECG telemetry transmitters (T12S or T12 Transmitters), the compatible receivers combined with an antenna network and a compatible multi-parameter Central Station software application running on a PC.

The T12 incorporates wireless electrocardiographic technology to achieve acquisition and RF transmission of simultaneous real-time 12-lead ECG data with diagnostic quality to a Mortara receiver module while allowing the patient to be ambulatory. It provides a means to acquire and transmit 12-lead cardiac signals to a compatible monitoring device where the signals are displayed, without direct connection to an electrocardiograph.

The T12S integrates wireless electrocardiographic and pulse oximetry technology in one device to achieve real-time acquisition and RF transmission of simultaneous 12-lead ECG data with diagnostic quality and pulse oximetry measurement values and waveform data to a Mortara receiver module while allowing the patient to be ambulatory . It provides a means to acquire and transmit 12-lead cardiac signals and pulse oximetry measurement to a compatible monitoring device where the signals are displayed without direct connection to an electrocardiograph or

separate pulse oximeter device. The T12/T12S affords the patient complete freedom of movement. Unlimited range can also be obtained with the addition of Mortara antenna network units.

T12 / T12S Transmitters are designed to work with real-time efficiency within a multiple transmitter environment without interference. The individual transmitter can be configured on one of 256 specific channels and allows the user to increase or decrease the channels until the desired one is selected. A design option will allow the user to set the patient cable type to avoid unused leads generating lead-fail messages. The selection will be 4, 5 or 10 lead-wires.

The unit operates from a single "AA"-type battery and has an internally integrated antenna which is not removable or accessible. It contains an LCD that is used for setup and status. During setup, it can display ECG waveforms and SpO2 data, patient demographics, and other user selectable options. A language option will allow the selection of the applicable user interface language. While in normal operation, the display will show status information such as a battery gauge and lead-fail information. The user can navigate through menu options and turn the unit on and off. A front button functions as a patient alert button in normal use.

The patient hookup acquires a continuous 12-lead ECG signal. The signal is A/D converted and the digital data is sent to a compatible centralized monitor using wireless radiofrequency communication. The antenna network receives the data sent by the transmitters. The network delivers the signal to the receivers installed in a compatible Central Station PC. The receivers decode the data containing the ECG waveforms and status from the transmitters for monitor display and review.

Intended Use:

The T12S Transmitter is a non-invasive prescription device positioned for typical use within a clinical setting of ambulatory patients in a centralized monitoring system or other clinical settings where such telemetry is used. The T12S Telemetry Transmitter is a diagnostic tool intended to acquire, and transmit real time ECG and SpO2 data of ambulatory patients that require ECG monitoring during cardiovascular problematic situations.

The T12S is designed to be used in a multiple transmitter telemetry system without interference. Problematic patients are continuously monitored through telemetry, when moving in a defined area, of a variable size depending on layout and thickness of walls. In order to assure proper signal reception in each different situation, an antenna network can be installed according to customer needs.

When used within a compatible multi-parameter Telemetry Central Station system, the T12S Transmitter is designed to transmit ECG only or ECG and SpO2 data. A single patient can be selected for reviewing data in the single patient view, which includes the following displayed and printed data:

- All 12 real-time ECG leads.
- Current average and reference QRS complex with current ST levels for all leads

Indications for Use:

The T12S Telemetry Transmitter is a non-invasive prescription device

- indicated for use as a radiofrequency physiological signal transmitter that acquires and delivers RF transmission of real-time electrocardiographic and pulse oximetry diagnostic quality data obtained during physiologic stress exercise testing and ambulatory patient monitoring.
- indicated for use in a clinical setting, by qualified medical professionals, properly trained for ECG monitoring and use of the system. The personnel must be experienced in cardiovascular problematic situations and emergency procedures or pathologies related to cardiac involvements. The cardiac data and analysis provided is reviewed, confirmed, and used by trained medical personnel in the diagnosis of patients with various rhythm patterns.
- It is not intended as a sole means of diagnosis.
- indicated for use for continuous or spot monitoring of non-invasive arterial oxygen saturation monitoring.
- indicated for use on hospital patients of any age where ambulatory monitoring of ECG and SpO2 data is done (e.g. patients in Coronary Care Units, Step-Down Units, Emergency Departments, stress testing or rehabilitation departments).
- It is not designed for out of hospital transport.
- It is not designed for use in highly invasive environments, such as an operating theatre.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 4 2008

Ms. Laura Spiegelhoff
Manager of Quality Assurance and Regulatory Affairs
Mortara Instrument, Inc.
7865 North 86th Street
Milwaukee, WI 53224

Re: K081800
Trade/Device Name: T12S Telemetry Transmitter
Regulation Number: 21 CFR 870.2910
Regulation Name: Physiological Signal Radiofrequency Transmitters and Receivers
Regulatory Class: Class II
Product Codes: DRG, DQA
Dated: May 30, 2008
Received: June 25, 2008

Dear Ms. Spiegelhoff:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081800

Device Name: **Mortara T12S Telemetry Transmitter**

Indications for Use:

The T12S Telemetry Transmitter is a non-invasive prescription device

- indicated for use as a radiofrequency physiological signal transmitter that acquires and delivers RF transmission of real-time electrocardiographic and pulse oximetry data obtained during physiologic stress exercise testing and ambulatory patient monitoring.
- indicated for use in a clinical setting, by qualified medical professionals, properly trained for ECG monitoring and use of the system. The personnel must be experienced in cardiovascular problematic situations and emergency procedures or pathologies related to cardiac involvements. It is not intended as a sole means of diagnosis.
- The pulse oximetry sensor is indicated for use for continuous or spot monitoring of non-invasive arterial oxygen saturation monitoring.
- indicated for use on hospital patients of any age where ambulatory monitoring of ECG and SpO2 data is done (e.g. patients in Coronary Care Units, Step-Down Units, Emergency Departments, stress testing or rehabilitation departments).
- It is not designed for out of hospital transport.
- It is not designed for use in highly invasive environments, such as an operating theatre.

The cardiac data and analysis provided is reviewed, confirmed, and used by trained medical personnel in the diagnosis of patients with various rhythm patterns.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K081800

Page 1 of ____

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K081800